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December 29, 2005

Signature: 

(Sharon M. Signich)

Docket No.: 28335/40012  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Kelly R. Clark et al.

Application No.: 10/789,303

Filed: February 26, 2004

For: RECOMBINANT ADENO-ASSOCIATED  
VIRUS PRODUCTION

Confirmation No.: 8089

Art Unit: 1653

Examiner: M. Burkhardt

**INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

This Information Disclosure Statement is being submitted after receipt of the first office action on the merits but before the mailing of a final Office Action or Notice of Allowance. Therefore, our check in the amount of \$180.00 covering the fee set forth in 37 CFR §1.17(p) is enclosed. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 13-2855, under Order No. 28335/40012. A duplicate copy of this paper is enclosed.

Dated: December 29, 2005

Respectfully submitted,

By 

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PTO/SB/08a/b (08-03)

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Substitute for form 1449A/B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/789,303
Filing Date	February 26, 2004
First Named Inventor	Kelly Reed Clark <i>et al.</i>
Art Unit	1653
Examiner Name	M. Burkhart
Attorney Docket Number	28335/40012

Sheet	1	of	2
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**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		5,622,856	04-22-1997	Natsoulis	
		5,658,776	08-19-1997	Flotte <i>et al.</i>	
		5,658,785	08-19-1997	Johnson	
		5,837,484	11-17-1998	Trempe <i>et al.</i>	
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		6,365,403	04-02-2002	Natsoulis <i>et al.</i>	
		6,475,769	11-05-2002	Wilson <i>et al.</i>	
		6,541,258	04-01-2003	Allen <i>et al.</i>	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
		WO99/41399	08-19-1999	Wadsworth		

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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Aitken <i>et al.</i> , <i>Hum Gene Therapy</i> , "A Phase I Study of Aerosolized Administration of tgAAVCF to Cystic Fibrosis Subjects with Mild Lung Disease", 12:1907-1916 (2001)	
		Carter <i>et al.</i> , <i>AAV Vectors for Gene Therapy</i> , in <i>Gene and Cell Therapy: Therapeutic Mechanisms and Strategies</i> , Second Edition (Ed. N. Templeton-Smith), pp. 71-101, Marcel Dekker, New York, 2004	
		Clark <i>et al.</i> , <i>Hum Gene Therapy</i> , "Cell Lines for the Production of Recombinant Adeno-Associated Virus", 6:1329-1341 (1995)	
		Clark <i>et al.</i> , <i>Gene Therapy</i> , "A stable cell line carrying adenovirus-inducible rep and cap genes allows for infectivity titration of adeno-associated virus vectors", 3:1124-1132 (1996)	
		Clark <i>et al.</i> , <i>Hum Gene Therapy</i> , "Recombinant Adeno-Associated Viral Vectors Mediate Long-Term Transgene Expression in Muscle", 8(6):659-669 (1997)	
		Clark <i>et al.</i> , <i>Hum Gene Therapy</i> , "Highly Purified Recombinant Adeno-Associated Virus Vectors Are Biologically Active and Free of Detectable Helper and Wild-Type Viruses", 10(6):1031-1039 (1999)	
		Fan and Dong, <i>Human Gene Therapy</i> , "Replication of rep-cap Genes Is Essential for the High-Efficiency Production of Recombinant AAV", 8:87-98 (1997)	
		Gao <i>et al.</i> , <i>Molecular Therapy</i> , "Rep/Cap Gene Amplification and High-Yield Production of AAV in an A549 Cell Line Expressing Rep/Cap", 5(5):644-649 (2002).	
		Graham and Prevec, <i>Mol. Biotechnol.</i> , "Methods for Construction of Adenovirus Vectors",	

Examiner Signature		Date Considered	
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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/789,303
				Filing Date	February 26, 2004
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				Art Unit	1653
				Examiner Name	M. Burkhardt
				Attorney Docket Number	28335/40012
Sheet	2	of	2		

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<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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